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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,307	04/12/2001	Richard J. Whitbourne	32286-192724	3036

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,307

Applicant(s)

WHITBOURNE ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/15/04 ~~09/01/04~~.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/01/04</u> <u>7/15/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statement,

Remarks/Amendment dated 7/15/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 23-25, and 28-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Whitbourne et al (USPN 6,110,483 hereafter '483). The claims are drawn to a medicated device comprising a scaffold with surfaces in close proximity, and a coating on said surface comprising a therapeutic agent.

4. The '483 patent discloses a medical device comprising a substrate with a coating (abstract, col. 5, lin. 58-65). The substrates include commonly difficult substrates to coat such as wires, needles, urethral inserts and other implantable objects (*Ibid.*). The coating material

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comprises both hydrophilic and hydrophobic polymers such as N-vinylpyrrolidone (col. 5, lin. 13-39) and acrylic polymers (col. 6, lin. 5-16) as well as vinyl acetate (*Ibid.*), as well as polyvinylpyrrolidone/vinyl acetate copolymers (col. 3, lin. 38-50). The coating comprises pharmaceutical agents including rifamycin, and heparin complexes with benzalkonium chloride (col. 8, lin. 59-col. 9, lin. 28). The coatings, as a result of the drying process, intermingle with the substrates (col. 10, lin. 36-40). The coating composition has a thickness of about less than 50 microns (col. 7, lin. 15-20). According to applicant's specification a 10-micron thick coating would correspond to a 1000 microgram/cm³. The thickness of this coating would possess a loading amount well within the limits of the claimed invention. The reference discloses various methods of making the medical device including dipping, spraying and other well-known coating methods (col. 2, lin. 60-68). Though silent to the specific design of the substrates regarding their edges and surfaces, the coating is a continuous coating over each surface (col. 4, lin. 18-30).

5. Regarding claims 41 and 42, it is the position of the examiner that such limitations do not impart patentability to the claim. The reference discloses a polyvinylpyrrolidone/vinyl acetate copolymer as a possible coating material. It would be well within the limits of ordinary skill in the art to determine the optimal component ranges operation for the polymer coating giving the general conditions of the specification. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

6. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the

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invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

7. With these things in mind it would have been obvious to a skilled artisan to follow the suggestions of the art to produce a medical article with a continuous coating over all surfaces with a high loading concentration. One of ordinary skill in the art would have been motivated to follow these suggestions in order to provide a coated medical device that is flexible, and resist wet abrasions. It would have been obvious to follow these suggestions with an expected result of a coated medical device.

8. Claims 26,27,53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Whitbourne et al (USPN 6,110,483 hereafter '483) and Kamath et al (USPN 6,335,029 hereafter '029). The claims are drawn to a medical device comprising a substrate and a coating. The substrate is a coil, and the coating further comprises paclitaxel.

9. As discussed above the '483 patent discloses a medical device comprising a substrate and a coating. The substrates include wires, stents, and other implants (col. 2, lin. 31-38). The reference is however silent to the inclusion of coils as possible substrates. The reference is also silent to the inclusion of paclitaxel. However the inclusion of this antibiotic is well within the level of skill in the art, since many antibiotic agents are mentioned and suggested by the '483 reference. Their inclusion in a medical device is well within the art as seen in the '029 reference.

10. The '029 reference discloses a coated medical device comprising a substrate and a coating with antibiotics agent incorporated therein (abstract). The substrates may include coils,

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(col. 2, lin. 45-50), biocompatible polymer coatings such as polyvinylpyrrolidone (col. 6, lin. 28-50), and antibiotics such as paclitaxel (col. 5, lin. 54-65). Following these teachings a skilled artisan would have been motivated to include paclitaxel in to the coating compositions of '483. A skilled artisan would have further been motivated to apply the coatings to a coiled substrate following the suggestions of '029.

11. With these things in mind a skilled artisan would have been motivated to apply coating compositions to coiled substrates as taught and suggested by '029. A skilled artisan would have been motivated to continuously coat the coil as taught by '483 in order to provide a medical device with a coating that is flexible, and resist wet abrasions. A skilled artisan would have been motivated to include paclitaxel into the coatings of '483 as shown in '029 in order to further treat more bacterial infections. It would have been obvious to a skilled artisan to combine these teachings and suggestions with an expected result of a medical device with a flexible, and stable coating capable of treating various bacterial infections.

Response to Arguments

12. Applicant's arguments with respect to claims 23-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Whitbourne (USPN 6,306,176) teaches coated medical devices with various substrates and biocompatible polymers.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
